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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,087	12/19/2001	Timothy J Fischer	9250-5CTIP4XX	3082
7590	11/17/2004		EXAMINER	
Robert W. Glatz Myers Bigel Sibley & Sajovec, P.A. Post Office Box 37428 Raleigh, NC 27627			HUYNH, PHUONG N	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,087	FISCHER ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-21,23-40,42,43 and 45-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-21,23-40,42,43 and 45-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/21/03; 8/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 3-21, 23-40, 42-43, and 45-54 are pending.
2. The International Preliminary Examination Report on PTO 1449 filed 1/21/03 and International Preliminary Examination Report on PTO 1449 filed 8/26/04 (No 145) have been considered but have been crossed out because said reports are not appropriate to be printed on an issued patent. Further, the Downey et al reference (no. 26) and the Toh et al reference (no. 60) on PTO 1449 filed 12/19/01 have not been considered and crossed out because the journal title and date are missing on PTO 1449.
3. In view of the amendment filed 8/27/04, the following rejections remain.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1, 3-21, 23-40, 42-43, and 45-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for a method for diagnosis of disseminated intravascular coagulation (DIC) comprising the steps of (a) adding a metal divalent ion and one or more clot inhibitor to a blood sample from a patient to cause the formation of a complex comprising C reactive protein and at least one human lipoproteins selected from the group consisting of VLDL, and IDL, while causing no fibrin polymerization, (b) measuring the formation of said complex overtime so as to derive a time-dependent measurement profile, (c) determining the slope of and /or total change in the time-dependent measurement profile, and (d) correlating the formation of the precipitate to the likelihood of mortality, the greater the formation of said complex, the greater the likelihood of death of the patient, **does not** reasonably provide enablement for any methods as set forth in claims 1-49. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8

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USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only a method for diagnosis of disseminated intravascular coagulation (DIC) comprising the steps of (a) adding calcium as one of the divalent metal ion and one or more clot inhibitor to a blood sample from a patient to cause the formation of a complex comprising C reactive protein and at least one human lipoproteins selected from the group consisting of VLDL, and IDL, while causing no fibrin polymerization, (b) measuring the formation of said complex overtime so as to derive a time-dependent measurement profile, (c) determining the slope of and /or total change in the time-dependent measurement profile, and (d) correlating the formation of the precipitate to the likelihood of mortality. The specification discloses only Calcium and thrombin inhibitor PPACK as the reagents for the claimed method. The addition of calcium causes the formation of a precipitate in the sample and the greater the complex formation (precipitate) between c reactive protein (CRP) and VLDL or IDL (Figure 42, page 38, line 35), the greater severity of the patient's haemostatic dysfunction.

The specification does not teach how to make *any* one more "reagents" (claims 1, 18, 20, 32, 40 and 49), *any* inhibiting reagent (claim 32), *any* antibody capable of binding to *any* lipoprotein-acute phase protein binding site (claim 36) for a method of diagnosing *any* "condition" of the patient (Claim 1) or a method for testing the effectiveness of any therapeutic (claim 49). The term "reagent" or "inhibiting reagent" without the specific amino acid or chemical structure has no structure, much less function. Let alone predicting or correlating which "condition" of a patient associated with the formation of a complex (precipitate) over time comprising any lipoproteins and any acute phase protein, without causing any fibrin polymerization. There is insufficient guidance as to the structure of any "reagents", and any "inhibiting reagent". Given the indefinite number of reagents, there is insufficient working example demonstrating all undisclosed reagent and/or inhibiting reagent are effective for causing formation of complex between any acute phase protein and any human lipoprotein, in turn, would be associated with a specific condition in a patient.

Stryer *et al* teach that a protein is highly dependent on the overall structure of the protein itself and that the primary amino acid sequence determines the conformation of the protein (See enclosed appropriate pages). Given the indefinite number of undisclosed reagents, it is unpredictable which undisclosed one or more reagents would be useful for diagnose which condition in a patient.

With regard to antibody capable of binding to *any* lipoprotein-acute phase protein binding site, there is insufficient guidance as to which undisclosed lipoprotein the antibody binds, in turn, useful for diagnosis all condition in a patient. There is insufficient guidance as to the binding specificity of the antibody.

Ngo *et al* teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure/function will require guidance (See Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495).

Kuby *et al* teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Abaza *et al* teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular). Given the indefinite number of undisclosed antibody, it is unpredictable which undisclosed antibody is capable binding to which lipoprotein-acute phase protein binding site, in turn, would be useful for diagnosis of all condition such as impending death of a patient. Even if C reactive protein (CRP) forms complex with lipoprotein such as VLDL in the present calcium that could be measured over time, the formation of CRP-VLDL complex does not equate with impending death or mortality of all patient.

Row *et al* teach that acute phase protein such as C reactive protein forms complex with lipoprotein such as apoB, and VLDL in pathological condition such as atherosclerosis is calcium dependent and inhabitable by phosphoryl choline (See abstract, in particular).

Li et al teach that lipoprotein such as amyloid P forms complex with HDL and VLDL but not with LDL (See abstract, in particular). Given the indefinite number of condition to be diagnosed, there is insufficient guidance as to which lipoprotein forming complex with which

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lipoprotein is associated with which condition, in addition to adding which undisclosed reagents to be added in the claimed method.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of *Ex parte Aggarwal*, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

6. Claims 1, 3-21, 23-40, 42-43, and 45-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of *any* one more “reagents” (claims 1, 18, 20, 32, 40 and 49), *any* inhibiting reagent (claim 32), *any* antibody capable of binding to *any* lipoprotein-acute phase protein binding site (claim 36) for a method of diagnosing *any* “condition” of the patient (Claim 1) or a method for testing the effectiveness of any therapeutic (claim 49).

The specification discloses only a method for diagnosis of disseminated intravascular coagulation (DIC) comprising the steps of (a) adding calcium as one of the divalent metal ion and one or more clot inhibitor to a blood sample from a patient to cause the formation of a complex comprising C reactive protein and at least one human lipoproteins selected from the group consisting of VLDL, and IDL, while causing no fibrin polymerization, (b) measuring the formation of said complex overtime so as to derive a time-dependent measurement profile, (c) determining the slope of and /or total change in the time-dependent measurement profile, and (d) correlating the formation of the precipitate to the likelihood of mortality. The specification discloses only Calcium and thrombin inhibitor PPACK as the reagents for the claimed method. The addition of calcium causes the formation of a precipitate in the sample and the greater the

complex formation (precipitate) between c reactive protein (CRP) and VLDL or IDL (Figure 42, page 38, line 35), the greater severity of the patient's haemostatic dysfunction.

Other than the specific reagents calcium and thrombin inhibitor for a method of predicting an increased likelihood of system failure or mortality of a patient associated with disseminated intravascular coagulation, there is inadequate written description about the structure associated with function of any undisclosed "reagent" or "inhibiting reagent" without the specific amino acid or chemical structure, let alone predicting or diagnosing all condition such as increased the likelihood of mortality in patient.

With regard to antibody capable of binding to *any* lipoprotein-acute phase protein binding site, there is inadequate written about the binding specificity of the antibody, the structure of the immunogen, i.e., the binding site of which lipoprotein-acute phase protein without the specific amino acid sequence to which the antibody binds, in turn, the antibody is useful for diagnosis for all condition in patient. Given the indefinite number of undisclosed antibody binding to which undisclosed lipoprotein-acute phase protein, reagent, and/or inhibiting reagent, the claimed method for diagnosis of all condition such as impending death or mortality of a patient is not adequately described. Thus, Applicant was not in possession of the claimed genus. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. The following new grounds of rejections are necessitated by the amendment filed 8/27/04.
8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
9. Claims 1, 3-17, 49, and 52 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step in claim 1: correlating the increase in steepness of the slope with an increase likelihood of mortality associated with hemostatic dysfunction in the patient.

The omitted step in claim 49: correlating the decrease in complex formation with effectiveness of the therapeutic for treatment of hemostatic dysfunction.

The omitted step in claim 52” correlating the decrease of complex formation with effectiveness of a therapeutic for treatment of haemostatic dysfunction.

10. Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “if any” in claim 17 is indefinite.

Claim 18 is ambiguous and indefinite because it is not clear which “parameter of the plasma or serum” is being measured for the claimed method. Further, “if present” in claim 18 part (d) is indefinite.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 3-21, 23-39, and 49-54 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,429,017 B1 (filed Feb 4, 1999).

The ‘017 patent teaches a method of diagnosing hemostatic dysfunction such as disseminated intravascular coagulation with an inflammatory condition (see summary of the invention, col. 3, line 49, claim 29 of ‘017 patent, in particular) comprising addition of one or more reagents such as calcium, magnesium, manganese, iron or barium or calcium chloride which are divalent metal ion to a test sample such as blood or plasma (see col. 11, lines 50-61, col. 12, line 39-40, claims 13-14, 22-23 of ‘017 patent, in particular) in order to cause formation of a complex comprising C-reactive protein, measuring the formation of complex over time as to derive a time-dependent measurement profile (see claim 1, part b, in particular) and determining the slope or change and/or total change in the time-dependent measurement profile to diagnose hemostatic dysfunction in the patient (see claims of ‘017 patent, in particular). The addition of metal divalent cation to the plasma sample causes complex formation between C-reactive protein (CRP) and the human lipoprotein that are already in the patient’s plasma sample (see paragraph

bridging col. 12 and 13 of '017 patent, in particular). Further, the '017 patent further teaches CRP forms complex with lipoprotein such as low density lipoprotein (LDL), very low density lipoprotein (VLDL) (see col. 3, col. 1, de Beer reference therein, in particular). The reference method further comprises a clot inhibitor as part of the reagents such as one or more hirudin, heparin, PPAC, I2581 and antithrombin (see col. 12, line 41, claims 2, 16, 25, 30 of '017 patent, in particular). Claims 8-9 and 12 are included in this rejection because disseminated intravascular coagulation inherently causes death of the patient. The reference also teaches the method is performed in the absence of clot inducing reagents (see claim 5 of '017, col. 11, line 63-64, in particular). The reference method wherein formation of precipitate is measured at least once after time zero wherein the measurements are measured by optical transmission or absorbance (see Figure 1A and 1B, paragraph bridging col. 1 and 2, claim 12 of '017, in particular). A single endpoint measurement can also be made after time zero using latex agglutination assay (see col. 14, line 6-9, in particular). The reference wherein a single reagent such as calcium is used prior to taking measurement (see col. 1, lines 50-60, in particular). Claims 36-37 are included in this rejection because the '017 patent also teaches adding a reagent such as a ligand or antibody that is capable of binding specifically to C-reactive protein and the binding of antibody to C reactive protein inherently inhibits precipitate formation between C reactive protein and VLDL (see col. 3, line 36-45, col. in particular). Thus, the reference teachings anticipate the claimed invention.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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15. Claims 40 and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,429,017 B1 (filed Feb 4, 1999) as evident by Cabana et al (J Immunol 130(4): 1736-1742, PTO 1449) in view of Richter et al (Clinica Chimica Acta 261: 141-148; 1997; PTO 1449).

The teachings of the '017 patent have been discussed supra.

The invention in claim 40 differs from the teachings of the reference only in that the method for diagnosis or monitoring of a hemostatic dysfunction wherein the one or more reagents comprises a divalent metal cation and an acute phase protein.

Cabana et al teach inflammation induces changes in CRP and plasma lipoproteins such as VLDL. During acute phase response, CRP forms complex with VLDL (see abstract, in particular).

Richter et al teach that bedside C reactive protein is routinely measured in patient with inflammation due to viral or bacterial infection by the ability of CRP to agglutinate fat emulsions (complex with fat) in the presence of calcium (see page 145, discussion).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any acute phase protein such as CRP as taught by Cabana et al and Richter et al in addition to the calcium for a method for diagnosis or monitoring of a hemostatic dysfunction comprising inflammatory condition as taught by the '017 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Cabana et al teach CRP forms complex with VLDL (see abstract, in particular). Richter et al teach the amount of complex depends on the amount of CRP in the presence of calcium (see page 144, in particular). Further, it is an obvious variation of the teaching of the '017 patent by adding an acute phase protein as one of the reagent to determine the amount of VLDL or complex formation in the test sample knowing that CRP forms complex with VLDL.

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1, 3-21, 23-39, and 49-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6,429,017 (PTO 892). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims of the '017 patent are drawn to a generic method of diagnosing hemostatic dysfunction by adding a reagent such as calcium to a test sample and determining the complex formation of C-reactive protein.

The claims of instant application are drawn to a method of diagnosing hemostatic dysfunction comprising an inflammatory condition wherein the method comprising adding one or more reagents to a test sample from a patient comprising at least part of a blood sample from the patient in order to cause formation of a complex comprising at least C-Reactive protein and at least one human lipoprotein, while causing substantially no fibrin polymerization, wherein the one or more reagents comprises a divalent metal ion; measuring the formation of said complex over time so as to derive a time-dependent measurement profile; and determining a slope and/or total change in the time-dependent measurement profile so as to diagnose hemostatic dysfunction in the patient (species). The method step of adding calcium to induce the formation of C-reactive protein complex is the same as that of the method step in the '017 patent. Further, the '017 patent teaches that C-reactive protein forms complex with lipoproteins that are inherently present in the patient's plasma sample (see paragraph bridging col. 12 and 13 of '017 patent, in particular). Further, the '017 patent further teaches CRP forms complex with lipoprotein such as low density lipoprotein (LDL), very low density lipoprotein (VLDL) (see col. 3, col. 1, de Beer reference therein, in particular).

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18. No claim is allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.


21. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

November 12, 2004


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